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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/251,638	02/17/1999	HENRY DANIELL	922.6641P	3456	
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IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP 1650 MARKET ST			KUBELIK, ANNE R		
			ARTINE	DADED MARCHE	
SUITE 4900			ART UNIT	PAPER NUMBER	
PHILADELPHIA, PA 19103			1638		
				DATE MAN ED AMOS 1900	

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	09/251,638	DANIELL, HENRY			
Office Action Summary	Examiner	Art Unit			
	Anne R. Kubelik	1638			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on  2a) This action is FINAL. 2b) This  3) Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final.  nce except for formal matters, pro				
Disposition of Claims					
<ul> <li>4)  Claim(s) 1,3-5 and 8-12 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1,3-5 and 8-12 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:				

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## **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 February 2006 has been entered.

- 2. Claims 1, 3-5 and 8-12 are pending.
- 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4. The objection to the amendment filed 3 June 2005 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure is withdrawn in light of Applicant providing support in the form of submission of the references from which the paragraphs were taken.
- 5. The objection to claim 12 is withdrawn in light of Applicant's amendment of the claim.

## Claim Rejections - 35 USC § 112

6. Claims 1, 3-5 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 August 2005, as applied to claims 1, 3-5 and 8-10. Applicant's arguments filed 21 February 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to multitude of expression cassettes comprising nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once and cotton plants comprising any of a multitude of nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once.

The instant specification, however, only provides guidance for a nucleic acid encoding GVGVPGVGFPGEGFPGVGVPGVGFPGFGFP (paragraph 10.3), which comprises GVGVP twice.

The specification does not teach how to distinguish synthetic coding sequences from nonsynthetic ones, and does not teach any pentatpeptides other than GVGVP or VPGVG.

Given the claim breath and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once and cotton plants comprising them.

Applicant urges that those of skill in the art would understand what is meant by synthetic and non-synthetic, quoting the dictionary, and producing these sequences using oligomers is well-known, citing McPherson and Zhang (response pg 5-6).

This is not found persuasive because in order to know what is synthetic all nonsynthetic sequences must be taught. They are not. The specification does not teach how to distinguish synthetic coding sequences from nonsynthetic ones; that is it does not teach how distinguish infringing compounds from noninfringing ones. It is noted that the claims encompasses repeats other than GVGVP or VPGVG and include repeats with amino acids other than G, V and P.

Applicant urges that the specification provides guidance for GVGVPGVGFPGEGFPGVGVPGVGFPGFGFP, which comprises GVGVP twice and

polypeptides with 121 repeats of GVGVP, and these sequences may be made using PCR (response pg 6).

This is not found persuasive because no other sequences are taught. The specification does not teach a nucleic acid encoding repeats any other pentapeptide other than GVGVP. Even Urry et al, sent by applicant, only teach polymers containing the repeat GVGVP; other repeats are not taught.

Applicant urges that \$10 of the specification references papers making  $(GVGVP)_{121}$  (response pg 6-7).

This rejection as it applies to a nucleic acid encoding (GVGVP)<sub>121</sub> is withdrawn.

Applicant urges that cotton cultivars that can be regenerated after Agrobacterium-mediated transformation are taught in Trolinder et al, which were incorporated by reference (response pg 7).

This portion of the rejection is withdrawn.

7. Claims 1, 3-5 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 August 2005, as applied to claims 1, 3-5 and 8-12. Applicant's arguments filed 21 February 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once. In contrast, the

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specification describes no nucleic acid encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

The specification does not describe the structural features that distinguish synthetic sequences from nonsynthetic ones.

Hence, Applicant has not, in fact, described nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

Applicant urges that there are numerous examples of nucleic acids encompassed by claim 1, referring to the submitted references (response pg 8).

This is not found persuasive. All of the peptides taught by Urry et al repeat GVGVP, GFGFP or GFGVP. Peptides that repeat other pentapeptides are not taught in Urry et al. However, the claims encompass other pentapeptides, and proteins that have amino acids other than those pentapeptides.

Applicant urges that one of skill in the art could distinguish a synthetic sequence from a nonsynthetic one and could make them; the difference relates to the origin of the nucleic acid, whether they are produced artificially (response pg 8).

This is not found persuasive. In order to distinguish a synthetic sequence from a nonsynthetic one, all nonsynthetic ones would need to be described, or vice versa. What are the structural features that distinguish synthetic from nonsynthetic sequences? What are the structural features that correlate to origin?

Applicant urges that claims 4 and 8-12 recite specific sequences (response pg 8).

This is not found persuasive because the claims encompass proteins that have amino acids other than the recited pentapeptide.

8. Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 August 2005 as applied to claims 1, 3, 5 and 8. Applicant's arguments filed 21 February 2006 have been fully considered but they are not persuasive.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase ""The transgenic cotton plant of claim 1, wherein said gene encodes between 20-251 repeats of the amino acid sequence Gly-Val-Gly-Val-Pro (SEQ ID NO:2)". Thus, such phrases constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrases or to cancel the new matter.

Applicant urges that several examples of repeats in this range are disclosed in the application, and the range is implicit in the teachings (response pg 9).

This is not found persuasive. Applicant points to no pages or paragraphs in which support is provided. The support pointed to in the previous response, 121 repeats of GVGVP found on pg 2 of the provisional application, provides no support for 21-99 or 101-249 repeats.

9. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claim 12 is indefinite in its recitation of "cotton plant ... where the pentapeptide is repeated in multiples of ten". It is not clear if applicant means that the pentapeptide is repeated 10, 20, or 30 etc times or if the pentapeptide is repeated both 10 and 20 times, for example, in the same plant.

Applicant urges that the repeats are repeated 10, 20, or 30 etc times (response pg 9).

This is not found persuasive. If that is what Applicant means, then the claim should be so written.

10. Claims 1, 3-5 and 8-12 are free of the prior art, given the failure of the prior art to teach a cotton plant transformed with a gene or coding sequence that encodes a protein comprises at least one pentapeptide that is repeated at least once, wherein the gene or coding sequence does not occur in nature and given the failure of the prior art to teach an expression cassette for transformation of such plants, wherein the cassette comprises a fiber-specific promoter.

## Conclusion

11. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D. March 21, 2006

NNE KUBELIK, PH.D.